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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/506,543 | 10/13/2004 | Kjell Olmarker | 003301-175 | 1315 |

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| EXAMINER | |
|---|---|
| MONDESI, ROBERT B | |
| ART UNIT | PAPER NUMBER |
| 1653 | |

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/506,543 | OLMARKER, KJELL | |
| | Examiner | Art Unit | |
| | Robert B. Mondesi | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 25-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 25-48 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Restriction requirement mailed May 22, 2006 has been vacated in favor of the present restriction requirement.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 25, 36, 38, 47 and 48, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of said treatment, wherein said substance is a receptor antagonist and wherein said substance is systemically administered.

Group II, claim(s) 26 and 27 drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of said treatment, wherein said pro-inflammatory cytokine is selected from the group consisting of TNF, IL-1, IL-6, IL-8, IL-12, IL-15, IL-17, IL-18, GM-CSF, M-CSF, MCP-1, MIP-1, RANTES, ENA-78, OSM, FGF, PDGF, and VEGF.

Group III, claim(s) 28 and 29, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment for posttraumatic tissue injury, wherein the said posttraumatic injury is caused by surgery.

Group IV, claim(s) 30, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment for thermic injury.

Group V, claim(s) 31, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment for wound resulting from metabolic process due to reduced nutritional supply.

Group VI, claim(s) 32, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment for diabetic ulcer, a leg ulcer, a decubitus ulcer or a gastric ulcer.

Group VII, claim(s) 33, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment for a wound resulting from exposure to a toxic compound.

Group VIII, claim(s) 34, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment, wherein the said substance is a monoclonal antibody.

Group IX, claim(s) 35, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment, wherein the said substance is selected form a group consisting of infliximab, CDP-571, D2E7 and CDP-870.

Group X, claim(s) 37, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment, wherein the said substance is etanercept.

Group XI, claim(s) 39, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment, wherein the said substance is an antisense oligonucleotide.

Group XII, claim(s) 40, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment, wherein the said substance is MMP inhibitor selected from the group consisting of tetracyclines, chemically modified tetracyclines,

Prinomastat, Batimastat, Marimastat, KB-R7785, TIMP-1, TIMP-2, adTIMP-1, and adTIMP-2.

Group XIII, claim(s) 41, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment, wherein the said substance is an quinolones selected from the group consisting of Norfloxacin, Levofloxacin, Enoxacin, Sparfloxacin, Temafloxacin, Moxifioxacin, Gatifloxacin, Gemifloxacin, Grepafloxacin, Trovafloxacin, Ofloxacin, Ciprofloxacin, Pefloxacin, Lomefloxacin, and Temafloxacin.

Group XIV, claim(s) 42, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment, wherein the said substance is a thalidomide derivate selected from the group consisting of CC-1088, CDC-501, CDC-801 and Linomide.

Group XV, claim(s) 43, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment, wherein the said substance is selected from the group consisting of prostaglandins, phosphodiesterase 1, 11, 111, IV, and V-inhibitors, cyclosporin, pentoxifyllin derivates, hydroxamic acid derivates, melanin and melancortin agonists, and lazaroids.

Group XVI, claim(s) 44 and 45, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment, wherein the said substance is a specific IL-1.alpha. and/or IL-1.beta. blocking substance or a non-specific IL-1.alpha. and/or IL-1.beta. blocking substance.

Group XVII, claim(s) 46, drawn to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment, wherein the said substance is lactoferrin or a peptide derived or derivable from lactoferrin.

The inventions listed as Groups I-XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XVII appears to be that they all relate to a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment.

However, WO 89/05145 (Cited in the IDS filed October 13, 2004) teaches a method for treating a wound and/or improving wound healing wherein a therapeutically effective amount of a pharmaceutical composition comprising a substance that inhibits a pro-inflammatory cytokine is administered to a patient in need of a treatment; therefore the technical feature linking the inventions of Groups I-XVII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-XVII are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B. Mondesi

Robert B. Mondesi

5-19-06